



FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)

Hilton Washington D.C./Silver Spring

AUGUST 5, 2009

AGENDA

- 8:00 a.m. Call to Order and Opening Remarks
- Introduction of Committee
- Conflict of Interest Statement
- 8:15 a.m. *Topic 1: Status Update on Bioequivalence for Highly-variable drugs*
 Status update – there will be no Advisory Committee discussion of this topic
- 9:00 a.m. *Topic 2: Challenges in the Development of Transdermal Drug Delivery Systems (TDDS)*

 Committee discussions and recommendations
- 10:15 a.m. **BREAK**
- 10:30 a.m. *Topic 3: Classifying Pre-Surgical Preparations as Sterile Products*

 Committee discussions and recommendations
- 12:00 p.m. **LUNCH**
- 1:00 p.m. Open Public Hearing
- 2:00 p.m. *Topic 4: Status and Implementation of ICH Q8, Q9, and Q10 Quality Guidelines*
- 4:15 p.m. **Conclusion and Summary Remarks**
- 5:00 p.m. **ADJOURNMENT**